

REMARKS

Reconsideration of the rejections set forth in the Office action dated November 11, 2001 is respectfully requested. Submitted herewith is a one-month extension of time to extend the time for response to March 8, 2002.

I. Amendments

The specification has been amended to point out in the specification, the stent feature clearly seen in Figs. 1 and 3, that the distance between opposite sides of a wave segment in the contracted stent is at a minimum at a point intermediate opposite looped peaks, where opposite sides of a wave appear to be touching in the two figures. This feature is also inherent in stent and disclosed, since the "pinched" end in each loop, together with the rounded curve at the loop end itself, will force opposite legs in a wave segment closest together at a point between the opposite loops.

Claim 1 has been amended to include the above feature that the distance between opposite sides of a wave segment in the contracted stent is at a minimum at a point intermediate opposite looped peaks.

Claim 13 has been amended to introduce limitations relating to the stent construction, as requested by the Examiner.

No new matter has been added by these amendments.

II. Rejections under 35 U.S.C. §102

Claims 1 and 5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schnepf-Pesch et al. (5,860-999). Claims 1-5 stand rejected under 35 U.S.C. 102(e) as being anticipated by Duerig et al. (6,190,406). These rejections are respectfully traversed in view of the foregoing claim amendments and following remarks

A. Legal Standard for Anticipation (MPEP §2131)

It is well settled that "[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." PPG Industries, Inc. V. Guardian Industries Corp., 75 F.3d 1558, 1566, 37

USPQ2d 1618, 1642 (Fed. Cir. 1996), see *a/so* MPEP §2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 (Fed. Cir. 1987).

B. The Prior Art

1. (Schneep-Pesch) U.S. Patent No. 5,860,999 ("Schneep-Pesch") describes a stent which is formed by connecting areas of wire paths in a cylindrical fashion. The paths form a wave of loops with peaks defining the boundaries of the wave. The loops are then interconnected axially and can be arranged to form a continuous ring. Multiple rings are aligned such that the loops of sequential rings may be flexibly coupled.

The wire paths forming the wave-like patterns are characterized by straight segments between successive looped portions, and resemble a saw-tooth pattern in the expanded state, in which the portion of the wave-like pattern between a peak and trough is characterized by a substantially straight segment. See Schneep-Pesch Figure 3

Nowhere does this reference show a stent-wire wave pattern having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks of the wave.

On the contrary, and as noted above, in the expanded state of the reference stent, the waves form a V pattern, as seen in Fig. 3, which would create a substantially linear increase in distance between adjacent legs on proceeding from one peak to another. Further, in the contracted state, the distance between adjacent legs in a wave is substantially constant, as illustrated in Figs. 1 and 4.

Nor does the Schneep-Pesch reference disclose the particular advantages inherent in the presently claimed stent construction, as set out, for example, on page 7 line 30 to page 8 line 15. In particular, the present invention offers the advantage over a sawtooth pattern, such as disclosed in Schneep-Pesch, in that compression stresses and bending stresses are not concentrated at the sharp vertices of the waves, while still allowing the stent to be forced into a highly compressed, contracted state.

2. (Duerig) U.S. Patent No. 6, 190,406 B1 ("Duerig") describes a self expanding stent composed of tubular members made up of a plurality of adjacent hoops. The hoops comprise a cylindrical arrangement of longitudinal struts with opposing ends. The ends are curved forming a loop and connected together with other struts containing similar curved ends forming a V or sawtooth pattern in the expanded state (Fig. 5) and a U-shaped pattern in the contracted state (Fig. 4).

Nowhere does this reference show a stent-wire wave pattern having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks of the wave.

On the contrary, and as noted above, in the expanded state of the reference stent, the waves form a V pattern, as seen in Fig. 5, which results in a substantially linear increase in distance between adjacent legs on proceeding from one peak to another. Further, in the contracted state, the distance between adjacent legs in a wave is at a minimum at the ends of opposite loops, not at a position intermediate the loops, as seen clearly in Fig. 4.

Nor does the Duerig reference disclose the particular advantages inherent in the presently claimed stent construction, as set out for example, on page 7 line 30 to page 8 line 15, for the same reasons discussed above with respect to the Schneep-Pesch reference.

C. Analysis

Neither of the cited references to Schneep-Pesch or Duerig disclose the features, in an expandable stent of:

(i) a stent-wire wave pattern having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween,

(ii) a stent-wire pattern having a wave shape such that in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks of the wave.

Since neither reference discloses each and every limitation of claimed invention, as embodied in claims 1 and 5, neither of the two references anticipates the claimed invention. The applicants therefore submit that claims 1 and 5 are novel over the cited references, under 35 U.S.C. §102.

III. Rejections under 35 U.S.C. §103(a)

Claims 6-10 and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (6,190,406). Claims 8-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schnepf-Pesch et al. (5,860,999) and Parodi (5,954,764). This rejection is respectfully traversed in view of the following remarks

A. The claimed invention

All of the rejected claims include the limitations present in claim 1, of

(i) a stent-wire wave pattern having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween,

(ii) a stent-wire pattern having a wave shape such that in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks of the wave.

As noted above, and discussed in the specification, e.g., on page 7, line 30 to page 18, and page 12, lines 13-29, these stent wire features provide a unique combination of advantages not shown or suggest in the prior art. In particular:

1. The stent can be forced into a highly compressed or contracted configuration, with relatively little stress in the peak regions, by virtue of the pinched configuration of the peaks, in contrast to a saw-tooth like pattern where stresses are concentrated in the peak regions of the wire.

2. At the same time, the stent can undergo a several-fold radial expansion by virtue of the ability to be close packed in a contracted configuration, unlike a sine wave pattern where the amount of compression at the peaks is limited.

3. Radial expansion of the stent produces little change in the overall length of the stent.

B. The Prior Art

Neither Schriepp-Pesch or Duerig disclose the claimed stent-wire pattern features, or the advantages obtained thereby, for the reasons discussed above.

Parodi is not concerned with the construction of an endovascular stent, nor is one disclosed having the features of the instant stent of claim 1. Nor does Parodi suggest the advantages to be obtained by the presently claimed stent.

C. Analysis

Since none of the cited references shows or suggests the advantages of the stent construction recited in claim 1, and embodied in claims 6-10 and 12, and 8-12, the cited art cannot be held to render the claims obvious. The applicants therefore submit that claims 6-10 and 12 are patentable over the cited references, under 35 U.S.C. §103(a).

IV. Claims 13-17

The Examiner has indicated that claims 13-17 would be allowable over the prior art if amended to include the limitations of base claim 1.

Claim 13 has been amended to include certain structural features of the stent. Since the patentability of claim 13 does not appear to reside in the novel features of the stent now included in amended claim 1, these features have not been included in amended claim 13.

V. Conclusion

In view of the foregoing amendments and arguments, the applicants submit that the claims now pending in the application are in condition for allowance. Accordingly,

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reconsideration and withdrawal of the rejections set forth in the Office action dated November 11, 2001 are respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made." If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4401.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO THE SPECIFICATION

Page 7, lines 15-29.

This feature is illustrated particularly in Fig. 5A, which shows three adjacent wave segments, including segment 18 in its expanded (or expanding) form. Distances between opposite sides 36, 38 of wave segment, such as distances 40, 42, 44, are shown for a number of points between looped peak 46 in segment 18 and opposite looped peaks 48 in segment 18 and 50 in adjacent segment 20. In the plot shown in Fig. 5B, the x-axis represents the distance from a peak in a wave segment to the opposite peak of the wave segment, with the ordinates 40, 42, 44 in Fig. 5A shown. The distance along the y-axis represents the distance between opposite sides of the wave segment. As seen, the plot shows a relatively small slope ($\Delta x/\Delta y$) in the wave regions adjacent the peaks and the greatest slope in the center region of the segment between the looped peaks. The point of greatest slope, corresponding roughly to midpoint 42 between the peaks, is an inflection point in the plot, as the slope of the plot increases between points 40 and 42, then begins to decrease between points 42 and 44. Further, with reference to Figs. 1 and 3, the distance between opposite sides of a wave segment in the contracted state is at a minimum at a point intermediate the looped peaks, where opposite sides of a wave appear to be touching in the two figures.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO THE CLAIMS

1. (Amended) A stent designed for catheter delivery to a target neurovascular site via a tortuous path in a contracted state, and deployment at the target site in an expanded state, comprising

a plurality of expandable tubular members, each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks and having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave [in the stent's expanded state,] on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point therebetween, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks, and

axial connectors joining adjacent tubular members,

wherein radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one another, without significant change in the axial dimension of the stent.

2. The stent of claim 1, wherein the wire elements are formed of a NiTi shape memory alloy, and said radial expansion is achieved by releasing the stent from such catheter.

3. The stent of claim 2, which has a stress-induced martensite phase at body temperature.

4. The stent of claim 2, which has an austenite phase transition temperature below body temperature.

5. The stent of claim 1, wherein the connectors connecting adjacent tubular members are attached to confronting peaks of the adjacent members, and the

connectors are spaced from one another by intervening, unconnected confronting peaks.

6. The stent of claim 5, which can be carried in a distal end region of a catheter having a lumen inner diameter between about 0.5 and 2 mm, and adapted to be placed at the target site via a tortuous vascular path in the brain.

7. The stent of claim 1, wherein the stent in its contracted state has an inner diameter of between 0.5 and 2 mm, and the stent diameter in its expanded state is between 2-9 times that in its contracted state.

8. A system for treating a aneurysm or other vascular abnormality in a neurovascular target vessel having an inner diameter less than about 8 mm and accessible via a tortuous vascular path, comprising

a guide wire that can be deployed at the target site,

a catheter having a lumen inner diameter of 0.5 to 2 mm and a distal end region in the lumen, and adapted to be placed at the target site via such path,

the stent of claim 1 adapted to be carried in its contracted state within the catheter's distal end region, where the catheter and stent carried therein are adapted to be moved axially along the guide wire, for placing the catheter at the target site, and

a pusher wire movable through the catheter, for forcing the stent out of the catheter into the vascular site, where stent radial expansion to its expanded state is effective to lodge the stent at the target site.

9. The system of claim 8, wherein the stent wire elements are formed of a NiTi shape memory alloy, and said radial expansion is achieved by releasing the stent from such catheter.

10. The system of claim 9, wherein the stent is held in its contracted state in a stress-induced martensite state.

11. The system of claim 8, which further includes a stabilizer attached to the distal end of the pusher wire, engageable with the stent when forcing the same from the catheter.

12. The system of claim 8, wherein the stent in its contracted state has an inner diameter of between 0.5 and 2 mm, and a diameter in the expanded state of between 2-9 times that in the contracted state.

13. (Amended) A method of treating an aneurysm or other vascular abnormality in a neurovascular target vessel having an inner diameter less than about 8 mm and accessible via a tortuous vascular path, comprising

navigating a guide wire to the target site,

moving over the guide wire, a catheter having a lumen inner diameter of 0.5 to 2 mm and a distal end region in the lumen, and [the] a stent carried in [its] a contracted state within the catheter's distal end region, until the catheter distal end is located at the target site, said stent being formed of (i) a plurality of expandable tubular members, each member being composed of a continuous wire element forming a plurality of wave segments, and (ii) axial connectors joining adjacent tubular members, and radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one another, without significant change in the axial dimension of the stent,

replacing the guide wire with a pusher wire, and

using the pusher wire to force the stent out of the catheter into the vascular site, where stent radial expansion to its expanded state is effective to lodge the stent at the target site.

14. The method of claim 13, wherein the stent wire elements are formed of a NiTi shape memory alloy, and said radial expansion is achieved by releasing the stent from such catheter.

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15. The method of claim 14, wherein the stent is held in its contracted state in a stress-induced martensite state.

16. The method of claim 13, wherein the pusher wire is equipped at its distal end with a stabilizer that is engageable with the stent when forcing the same from the catheter.

17. The method of claim 13, wherein the stent in its contracted state has an inner diameter of between 0.5 and 2 mm, and a diameter in the expanded state of between 2-9 times that in the contracted state.